UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,157	09/19/2003	Kenneth W. Whitley	P-5655/5	7091

26253 7590 12/12/2006

DAVID W. HIGHET, VP AND CHIEF IP COUNSEL
BECTON, DICKINSON AND COMPANY
1 BECTON DRIVE, MC 110
FRANKLIN LAKES, NJ 07417-1880

EXAMINER	
BOWERS, NATHAN ANDREW	
ART UNIT	**PAPER NUMBER**
1744	

DATE MAILED: 12/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/666,157	WHITLEY, KENNETH W.	
	Examiner	Art Unit	
	Nathan A. Bowers	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,6-11,13 and 14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 4, 6-11, 13 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1) Claims 1, 4 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Witt (US 4810652) in view of Land (US 3630849).

With respect to claims 1, 4 and 8, Witt discloses a stackable roller bottle for cell growth culturing comprising an elongate cylindrical wall having a closed bottom end (Figure 1:30) and an opposed projecting neck portion (Figure 1:15) defining a liquid opening. The closed bottom end includes an inwardly directed recessed portion (Figure 1:32) for accommodating a neck portion end of an adjacent stacked similar container. This is disclosed in column 3, lines 35-68. Furthermore, the recessed portion includes a planar surface having at least one rib (Figure 1:38) extending therefrom for defining a space between the neck portion of one container and the planar surface of another. Witt, however, does not disclose that the side wall is configured so that a gap is defined between the side wall and an accommodated cap, or that an air space exists between the top of the cap of one container and the recessed portion of an associated second container.

Land discloses a cell culture container comprising a closed top end and a closed bottom end. The bottom end includes an inwardly directed recessed portion for accommodating the top portion of an adjacent stacked similar container. The recessed portion further includes a planar surface and sidewalls. A plurality of ribs is provided on the container for defining a space between the top end of the similar container and the planar surface of the original container. This is disclosed in Figures 1 and 2, and in column 2, lines 29-42.

Witt and Land are analogous art because they are from the same field of endeavor regarding cell culture devices.

At the time of the invention, it would have been obvious to replace the rib disclosed by Witt with the ribs set forth by Land. In column 2, lines 39-42, Land indicates that ribs capable of facilitating air flow between adjacent stacked containers is beneficial because increased

circulation promotes the maintenance of a uniform temperature during the culturing process. In view of the Land reference, only minor alterations would be necessary in the design of Witt in order to create ribs within the recessed portion that allow for efficient air circulation.

With respect to claims 9 and 10, Witt and Land disclose the apparatus set forth in claim 1 as set forth in the 35 U.S.C. 103 rejection above. In addition, Witt teaches that the bottle neck includes integral external screw threads (Figure 1:24) for receiving an internally screw threaded cap (Figure 1:20). The cap has a top surface and an annular outer skirt extending from the top surface to a bottom stop ledge.

2) Claims 2 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Witt (US 4810652) in view of Land (US 3630849) as applied to claim 1, and further in view of Kayal (US 5695987).

Witt and Land disclose the bottle assembly set forth in claim 1 as set forth in the 35 U.S.C. 103 rejection above, however do not expressly disclose that the space between the two coupled containers permits gases to enter into and out of the liquid opening of the adjacent stacked container, or that the cap further includes a central orifice with an affixed gas permeable membrane.

Kayal discloses a cell culturing roller bottle (Figure 1:12) comprising a liquid opening that is covered by a screw cap. The cap includes a central orifice covered by a gas permeable membrane (Figure 3:56), and allows gases to enter into and out of the liquid opening. This is disclosed in column 1, lines 54-67.

Witt, Land and Kayal are analogous art because they are from the same field of endeavor regarding cell culture devices.

At the time of the invention, it would have been obvious to alter the invention disclosed by Witt and Land in order to allow the space between the two coupled containers to permit the entry of gases into the liquid opening of the adjacent, bottom container. The addition of gases to a culturing vessel is often essential because many microorganisms require certain gases such as oxygen to grow. Kayal discloses in column 4, lines 6-17 that bottle caps comprising gas permeable membranes are an effective way to deliver critical gases to the culturing cells while preventing the passage of undesirable microorganisms and contaminants.

3) Claims 6, 7, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Witt (US 4810652) in view of Land (US 3630849) as applied to claim 12, and further in view of Pedmo (US 6585123).

Witt and Land disclose the roller bottle assembly set forth in claims 1 and 10 as set forth in the 35 U.S.C. 103 rejections above, however do not disclose that a plurality of ribs are provided that are equally spaced apart and radiate from a point proximal to the longitudinal axis of the container.

Pedmo discloses a bottle comprising an inwardly directed recessed portion at the bottom of the bottle. Ribs (Figure 5:34) are provided, which radiate from a point proximal to the longitudinal axis of the container toward the sidewall of the recessed portion. A plurality of equally spaced apart ribs is provided. This is disclosed in column 2, lines 46-58.

Witt, Land and Pedmo are analogous art because they are from the same field of endeavor regarding the use of capped bottles to contain a fluid.

At the time of the invention, it would have been obvious to utilize a plurality of equally spaced apart, outwardly radiating ribs in the roller bottle assembly disclosed by Witt. In column 1, lines 11-20, Pedmo discloses that ribs constructed in this manner are beneficial because they improve the strength properties of the bottles, thus enabling the bottles to withstand damage when physically struck. Pedmo additionally states that a plurality of ribs that radiate from the center of the bottle help the bottles withstand deformation during heat applications. Since incubation is sometimes completed under high temperatures, the utilization of ribs of this nature would be beneficial in the roller bottle assembly disclosed by Witt.

Response to Arguments

Applicant's arguments filed 10 October 2006, with respect to the 35 U.S.C. 102 rejections involving Pedmo have been fully considered and are persuasive. Therefore, the rejection has been withdrawn.

Applicant's arguments filed 10 October 2006, with respect to the 35 U.S.C. 103 rejections involving the combination of deLarosiere and Der Yuen have been fully considered and are persuasive. Therefore, the rejection has been withdrawn.

Applicant's arguments filed 10 October 2006, with respect to the 35 U.S.C. 102 rejections involving Witt have been fully considered and are persuasive. Therefore, the rejection

has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the combination of Witt and Land.

The Land reference addresses the deficiencies of the Witt reference by indicating that it is known in the cell culture art to stack adjacent containers using ridges that facilitate the circulation of air between the containers. Accordingly, Land discloses sidewalls that define a gap between the sidewall and an accommodated cap. Land also indicates that the gap is in communication with the space between the top of one container and the bottom of the other.

Since the combination of Witt and Land allows for gas circulation between adjacent stacked containers using multiple ridges, one of ordinary skill in the art would have found it obvious to expand on this design by providing the container caps with gas permeable membranes. The Kayal reference indicates that the addition of gases to a culturing vessel is often essential because many microorganisms require certain gases such as oxygen to grow. Kayal discloses in column 4, lines 6-17 that bottle caps comprising gas permeable membranes are an effective way to deliver critical gases to the culturing cells while preventing the passage of undesirable microorganisms and contaminants.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan A. Bowers whose telephone number is (571) 272-8613. The examiner can normally be reached on Monday-Friday 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on (571) 272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NAB

GLADYS JP CORCORAN
SUPERVISORY PATENT EXAMINER